Attorney Docket No. 9391-2

**PATENT** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Helmut Heide et al. Application No.: 10/085,526 Filed: February 26, 2002

Confirmation No.: 1405 Group Art Unit: 1755 Examiner: Karl E. Group

For: Resorbable Bone Replacement and Bone Formation Material

Date: September 2, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §1.97(c)

Sir:

Attached is a list of documents on form PTO-1449. Copies of certain documents, identified as documents AD-AF are not being furnished since they were submitted with the original form PTO 1449 (and we have used the same reference numbers on the instant form PTO 1449). Regarding a concise statement for document AN, this document is in French and is believed to be directed to the filling of bone defects with tricalcium phosphate beta in traumatology and is believed to relate to the use of BIOSORB beta-tricalcium phosphate ceramic (allegedly 45% porosity - 250-400 µm pore size) per a 510(k) Premarket Notification K021963. A copy of the sheet of the referenced Premarket Notification that identifies this article is attached to reference AN.

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. § 1.97(c), before final Office Action or Allowance, whichever is earlier. In accordance with the requirements of 37 C.F.R. § 1.97(c)(2), the Commissioner is authorized to charge the \$180.00 fee specified in 37 C.F.R. § 1.17(p) to Deposit Account No. 50-0220. This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted

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Rosa Lee Brinson

| Substitute form 1449A/PTO         |      | Complete if Known      |                     |  |
|-----------------------------------|------|------------------------|---------------------|--|
| INFORMATION                       |      | Application Number     | 10/085,526          |  |
| INFORMATION D                     |      | Filing Date            | February 26, 2002   |  |
| STATEMENT BY APPLICANT            |      | First Named Inventor   | Helmut Heide et al. |  |
|                                   |      | Group Art Unit         | 1755                |  |
| (use as many sheets as necessary) |      | Examiner Name          | Karl E. Group       |  |
| Sheet A                           | of A | Attorney Docket Number | 9391-2              |  |

| Examiner Cite | Cite No.    | U.S. Patent Document |                         | Name of Patentee or Applicant of Cited | Date of Publication of Cited |
|---------------|-------------|----------------------|-------------------------|--|------------------------------|
|               |             | Number               | Kind Code<br>(if known) | Document                               | Document<br>MM-DD-YYYY       |
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|   |             |  |                                       | FOREIGN PA              | TENT DOCUMENTS                              |                                 |          |
|---|-------------|--|---------------------------------------|-------------------------|---|---------------------------------|----------|
|   | Cite<br>No. | Foreign Patent Document  |                                       |                         | Name of Patentee or Applicant of Cited      | Date of Publication             | Т        |
|   |             | Office   | Number                                | Kind Code<br>(if known) | ·   | of Cited Document<br>MM-DD-YYYY |          |
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|   |             |  |                                       | <u> </u>                |   |                                 |          |
|   |             | <u> </u>   | OTHER                                 | NON PATENT              | LITERATURE DOCUMENTS                        |                                 |          |
| xaminer<br>nitials*   | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published   |                                       |                         |   |                                 | T        |
|   | AD          | DeGroot et al., <i>Die klinische anwendbarkeit von Calciumphosphat-Keramiken,</i> Zahnarztliche<br>Mitteilungen Heft 18/85, 75. Jahrgang (1985, pages 1938-1940  |                                       |                         |   |                                 |          |
|   | AE          | Roempp Chemie-Lexikon ed. 7 (1975, Franckhsche Verlagsbuchhaltung Stuttgert  |                                       |                         |   |                                 | -        |
|   | AF          | Koster, K. Heide H. Konig R., Histologische Untersuchungen an der Grenzflache zwischen Knochengewebe und Calciumphosphat-, Calciumaluminat- und Aluminiumoxidkeramik, Z. Orthop. 115 (1977), pages 893-699   |                                       |                         |   |                                 |          |
|   | •           | Peters, Dr   | . Fabian, Curasa                      | n Concise Stater        | nent of articles AD, AE and AF              |                                 | <u> </u> |
|   | AG          | Erbe et al., Comparison of Vitoss and Pro Osteon 500R in a Canine Model at 1 Year, 47th Annual Meeting, Orthopaedic Research Society (February 25-28, 2001), p. 0975  510(k) Summary Vitoss M Scaffold Synthetic Cancellous Bone Void Filler, Summary of S&E, Vitoss Scaffold, Orthovita, Inc. (December 14, 2000) pages H1-H3 |                                       |                         |   |                                 |          |
|   | АН          |  |                                       |                         |   |                                 |          |
|   | AI          | Letter from Dept. of Health & Human Services re: Vitoss <sup>1M</sup> Scaffold Synthetic Cancellous Bone Void Filler (December 14, 2000), 2 pages  |                                       |                         |   |                                 |          |
| _   | AJ          | Indications  | for Use Stateme                       | nt, Vitoss 'M Sca       | affold Synthetic Cancellous Bone Void Fi    | ller, Vitoss Scaffold           |          |
|   | AK          | 510(k) Summary (November 26, 2002) 2 pages   |                                       |                         |   |                                 |          |
|   | AL          | Letter from Dept. of Health & Human Services re: Synthes chronOS Tricalcium Phosphate and Synthes Perfusion Syringe (November 26, 2002), 2 pages   |                                       |                         |   |                                 |          |
| AM Galois et al., Use of B-tricalcium phosphate Science Ltd., Foot and Ankle Surgery Dece |             |  |                                       | cium phosphate          | in foot and ankle surgery; a report of 20 i | cases, Blackwell                |          |
|   | AN          | Filling of Bone Defects with Tricalcium Phosphate Beta in Traumatology, In Ann Chir 2000 December; 125(10):972-81 (concise statement)  |                                       |                         |   |                                 |          |
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|-----------------------|-----------------|---|
| Examiner Signature    | Date Considered |   |
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.